



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,063	01/28/2002	Norihito Shimono	2002-0055A	8747
513 7590 02/07/2008 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER YOUNG, MICAH PAUL	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 02/07/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/048,063	<b>Applicant(s)</b> SHIMONO ET AL.	
	<b>Examiner</b> Micah-Paul Young	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 29,30,33,34,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29,30,33,34,37 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 29, 30, 33, 34, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Lerner et al (USPN 5,840,332 hereafter '332) in view of Dutkiewicz et al (USPN 6,197,322 hereafter '322). The claims are drawn to a process of making a solid product comprising a core, first layer comprising a water-insoluble polymer

having chitosan dispersed therein, and an enteric coating, wherein the process comprising coating the core and evaporating the ethanol or water by drying.

5. The '332 patent discloses a solid formulation comprising a core and successive coatings (abstract). The coating composition comprises a water-insoluble carrier with a particulate dispersed therein (col. 9, lin. 38-65). The particulate matter is chitosan, and the water-insoluble include well known such as various Eudragit polymers along with ethylcellulose (*Ibid.*). The form further comprises an enteric coating (claim 4). The enteric coating comprises well-known enteric polymers including those based on methacrylic acid and methyl methacrylate copolymer (claim 17). The dosage form comes as a tablet, or pill, or capsule (abstract), and is designed for colonic delivery (col. 6, lin. 57-65). The reference teaches method of producing the coatings including dispersing the solid particulates in the water-insoluble polymer and coating a core pellet (examples). Ethanol is used as a solvent for the coating layer and is driven off by drying (examples).

6. The reference differs from the claims in its exemplified particulate matter and the ratio at which the particles are present in the coating layer. The claims recite a range from 1:4-4:1, where the claims exemplify a ratio from 1:1-3:7. However the 3:7 ratio is encompassed within the wider range of the claimed ratio. Further it remains the position that such modulations in ratio are merely an optimization of ranges. The process of the '332 patent provide sustained release (Figures) of a coated solid dosage form. Also the resulting products are within the same field of endeavor and solve the same problem. It remains the position of the Examiner that the general condition of the claims have been met by the '332 patent.

7. The reference also is silent to the specific particle size of the chitosan powder. Chitosan powder is a common ingredient in coating materials as is known in the art as seen in the '322 patent. The '322 patent discloses a chitosan coating suspension comprising chitosan particles ranging in size from 0.1-80 microns (col. 3, lin. 25-35). The powder suspension is applied to hydrophobic and/or hydrophilic polymers such as polyethylene and polyamides copolymers (col. 3, lin. 1-5). It would have been well within the level of skill in the art to apply the chitosan suspension to the coating method of the '332 patent in order to provide a better surface area and more adhesion to the surface of the core.
8. With these things in mind it would have been obvious to combine the chitosan suspension of the '322 patent into the coating composition of the '332 in order to provide an even coating and improve the release of the active agent in the core. It would have been well within the level of skill in the art to make this combination with an expected result of a stable and useful controlled release composition.

#### ***Response to Arguments***

9. Applicant's arguments with respect to claims 29, 30, 33, 34, 37 and 38 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

Application/Control Number:  
10/048,063  
Art Unit: 1618

Page 5

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young  
Examiner  
Art Unit 1618

  
MP Young

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER